

Research Article

A new lumbar fixation device alternative to pedicle-based stabilization for lumbar spine: *In vitro* cadaver investigation

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Context: To evaluate the stability provided by a new bilateral fixation technique using an *in vitro* investigation for posterior lumbar segmental instrumentation.

Design: Experimental cadaver study. In this study, we propose an alternative technique for a posterior lumbar fixation technique called “inferior-oblique transdiscal fixation” (IOTF).

Setting: Study performed at Engineering Center for Orthopedic Research Excellence (ECORE) in Toledo University-Ohio.

Participants: Six human lumbar cadaveric specimen used in this study.

Interventions: In this study, we propose an alternative technique for a posterior lumbar fixation technique called “inferior-oblique transdiscal fixation” (IOTF). As a novel contribution to the classical technique, the entry point of the screw is the supero-lateral point of the intersecting line drawn between the corpus and the pedicle of the upper vertebra. This approach enables the fixation of two adjacent vertebrae using a single screw on each side without utilizing connecting rods.

Outcome Measures: Flexion (Flex), extension (Ext), right and left lateral bending (LB & RB), and right and left axial rotation (LR & RR), and the position data were captured at each load step using the Optotrak motion measurement system and compared for IOTF and posterior transpedicular stabilization.

Results: The Posterior stabilization system (PSS) and IOTF significantly reduced the ROM of L4-L5 segment compared to intact segment's ROM. During axial rotation (AR) IOTF fused index segment more than PSS. Besides this, addition of transforaminal lumbar interbody fusion (TLIF) cage improved the stabilization of IOTF system during flexion, extension and lateral bending. Whereas, PSS yielded better fusion results during extension compared to IOTF with and without interbody fusion cages.

Conclusions: We hypothesized that the new posterior bilateral system would significantly decrease motion compared to the intact spine. This cadaver study showed that the proposed new posterior fusion technique IOTF fused the index segment in a similar fashion to the classical pedicle screw fusion technique.

Keywords: Lumbar fusion, Posterior fixation, Pedicle screw fixation, Bilateral system, *In vitro* lumbar, Lumbar spine

Introduction

Posterior lumbar segmental instrumentation using pedicle screws has long been used by spine surgeons for fixation in degenerative spine diseases, trauma and congenital/acquired spinal deformities. Posterior

stabilization was first described by Albee for the treatment of Pott disease in 1911, and Hibbs described the same technique for degenerative instability in the same year.^{1,2} This technique could be described as interspinous posterior fixation since autografts were placed between the decorticated spinous processes. In 1934, Mixter and Barr³ hypothesized that lumbo-sciatalgia was caused by disc herniation and that the most durable and effective treatment would be “a crude

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pure fusion technique". In 1962, Harrington⁴ proposed a novel method for treating scoliosis. Harrington's method involved the use of metal rods and hooks for providing stability to the spine along with correcting the curvature of the spine. Later, these rods became known as "Harrington rods". These rods were commonly used during the subsequent 30 years for scoliosis, degenerative spine and instability surgeries. A technical paradigm shift in spinal instrumentation was achieved by the introduction of transpedicular screws. Today's commonly used contemporary transpedicular screwing technique was first used in 1970 by Roy-Camille *et al.*⁵ and in 1984 by Cotrel and Dubousset.⁶ Anatomical landmarks are well defined for pedicle screw insertion, and real-time image guidance by intraoperative computed tomography has improved the accuracy of screw trajectory. However, significant malposition or inadvertent course of screws remains a major concern among spine surgeons.^{7,8}

Lumbar pedicle screw-based fixation is usually accomplished by open surgery; however, percutaneous lumbar surgery is also performed, as reported in the literature.^{9–12} The pedicle screw fixation technique, despite being the "gold standard", carries the risk of violation of the facet joint and excessive degeneration of the adjacent vertebrae.^{13–16} In addition, pedicle screws also carry the risk of screw loosening/failure, as reported in the literature.^{17–20} Over time, pedicle screw designs have varied. Currently, there are rigid screws and dynamic screws that can be used in conjunction with dynamic and/or rigid rods. However, posterior stabilization with dynamic screws in conjunction with rigid rods led to insufficient flexibility, and dynamic rods in conjunction with rigid screws led to screw loosening.²¹

The aim of this study was to compare a new bilateral fusion technique with the traditional pedicle screw fixation technique. Hence, we developed a new screw insertion technique as an alternative to the classical pedicle screw technique. We named this new technique "inferior-oblique transdiscal fixation" because this approach enabled fixation of two adjacent vertebrae

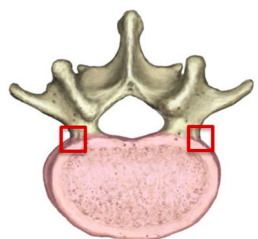
using a single screw on each side without utilizing connecting rods. In the current study, the biomechanics and limitations of this new screwing technique were tested and compared to those of the standard posterior transpedicular screw insertion technique with and without transforaminal interbody fusion cages using an *in vitro* cadaver testing method.

Materials and methods

Description of the "inferior-oblique transdiscal fixation" technique (IOTF)

The entry point of the lag screw in this new technique is the supero-lateral point of the intersection line between the corpus and the pedicle of the upper vertebra (Figure 1). From this point on, the lag screw (Figure 2) is directed toward approximately 30 degrees in the sagittal plane (*antero-inferior*) and 45 degrees in the coronal plane (*medio-inferior*) bilaterally; thus, the overall trajectory is oblique and antero-infero-medial (AIM) (Figure 3). This oblique inclination enables the screw to pass through the entire corpus of the upper vertebra, the intervertebral disc and the upper half of the lower vertebra.

As described earlier by Wiltse *et al.*²² a lumbar bilateral para-median skin incision five centimeters in length and bilateral paravertebral muscular blunt dissection between the plane of the multifidus and longissimus muscles are performed. The facet joints and transverse processes are exposed on both sides. As a novel contribution to the classical technique, the entry point of the screw is the supero-lateral point of the intersection line between the corpus and the pedicle of the upper vertebra. To expose this entry point, the lateral border of the pars interarticularis and the transverse process of the upper vertebra should be well visualized. Subsequently, the intertransverse ligament is incised over the attachment of the transverse process medially up to the lateral border of the pars interarticularis and then superiorly up to the inferior border of the upper transverse ligament to create an L-shaped flap reflected laterally. From this point on, the pedicle-corpus junction



Entry Point: Superolateral point of the intersecting line between the corpus and the pedicle

Figure 1 Picture of entry point demonstration.



Figure 2 Picture of prototype of screw used in study.

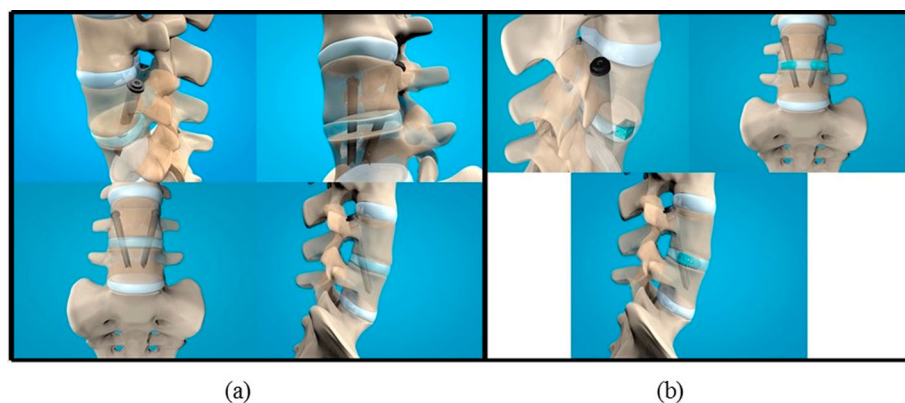


Figure 3 3-D illustration of application of new system screws (a) without TLIF and (b) with TLIF.

is identified by following the pedicle starting from the lateral aspect of the pars interarticularis. Then, the exiting nerve root is gently retracted laterally and the screw (Figure 1) is directed under the guidance of the O-arm or C-arm. When a transforaminal lumbar interbody fusion (TLIF) procedure is attempted in addition to these screws, the transverse process of the two lower vertebrae should also be exposed. For example, if we plan to stabilize L4-L5 segment using this new technique, L3 and L4 transverse processes should be exposed bilaterally; if we plan to add TLIF, we should additionally expose the L5 transverse processes bilaterally. When the plane passing through the vertebral end plates is assumed to be a reference horizontal plane (*axis*), the screw inclination is approximately 30 degrees in sagittal plane (*antero-inferior*) and 45 degrees in coronal plane (*medio-inferior*); thus, the overall trajectory is oblique and antero-infero-medial (*AIM*) (Figure 2). This oblique inclination enables the screw to pass through the entire corpus of the upper vertebra, the intervertebral disc and the upper half of the lower vertebra.

The new proposed surgical technique offers superiority in some aspects over the classical pedicle screw technique in terms of the following: easy revision surgery, absence of need for domino placement, tri-cortical

fixation and less risk of loosening of screws, safer trajectory with regard to the risks of dural sac and root injuries, shorter incision, less paravertebral muscle and soft tissue dissection; possibility of interbody fusion and shorter duration of hospitalization. The other advantage of this new technique is the fact that it does not require a longer learning curve.

A disadvantage of this new technique is the potential need of exiting nerve root retraction during the screw placement. On the other hand, this technique is not useful for deformity surgery because of the absence of correction maneuvers.

Biomechanical testing

We tested the efficacy of new technique (IOTF) for L4-L5 fusion and compared the results with those of the classical pedicle screw technique biomechanically at E-CORE (Engineering Center for Research Excellence, The University of Toledo). Six L2-S1 cadaveric specimens were obtained and tested in this study. Detailed information regarding the specimens is listed in Table 1. The DEXA T scores for these specimens ranged from -2.8 to -5.1. The spines were thawed, and the tissue surrounding the specimen, except for ligaments and discs, were carefully removed. The cranial (L2) and caudal (sacrum) ends of each specimen were potted using bondo (a 2-part epoxy resin). Potted sacra of each specimen were fixed on the testing apparatus located in the field of view of the Optotrak (NDI, Waterloo, Canada) motion capture system. LED (Light emitting diode) marker sets were attached to L2, L3, L4, L5 and the potted sacrum for recording the spatial locations in response to the applied moment using the Optotrak motion capture system. A loading fixture was attached to the potted cranial (L2) end and a torque transducer was attached to that fixture (Figure 4).

Each **intact** specimen was subjected to pure moments applied by the torque transducer in steps of 0, 2.5, 5, 7.5,

Table 1 Detailed specimen information.

Specimen ID	Age	Sex	T Score	Condition	Cause of death (COD)
66568	72	Female	-2.8	Osteoporosis	Lung cancer, COPD, Hypertension, Hyperlipidemia
66814	84	Male	-2.8	Osteoporosis	-
66310	77	Female	-5.1	Osteoporosis	COPD, Resp. failure
68153	87	Male	2.7	Normal	-
66267	57	Male	-3	Osteoporosis	Gunshot wound
65177	62	Female	-3.8	Osteoporosis	Cardiac arrest

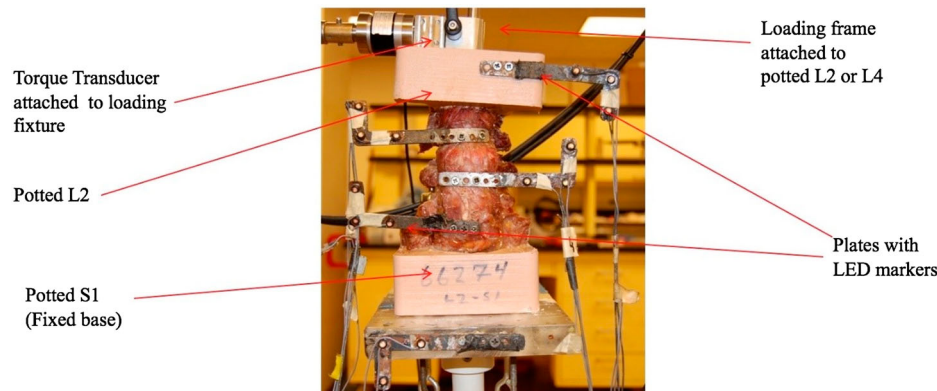


Figure 4 L2-Sacrum lumbar cadaveric specimen test setup.

10 and 0 Nm in flexion (Flex), extension (Ext), right and left lateral bending (LB & RB), and right and left axial rotation (LR & RR), and the position data were captured at each load step using the Optotrak motion measurement system (Figure 3). This system uses infrared cameras to track the spatial locations of three light-emitting diodes affixed to each vertebral body in response to the applied loads.

Following the testing of intact specimens, each L4-L5 was stabilized using a pedicle screw system (PSS) and was tested for range of motion (ROM). In the third step, the pedicle screws were removed and the IOTF screws were inserted bilaterally using the new technique and were tested for ROM. In the fourth step, both the IOTF screws were partially removed and TLIF cages were inserted bilaterally. The lag screws were reinserted (IOTF + TLIF cages) and tested for ROM. Finally, the IOTF screws were removed and pedicle screws of larger size were inserted and fixed, keeping the cages (PSS + TLIF cages), and were tested for ROM. Table 2 shows the implantation information for each specimen tested. Figure 5 shows the X-ray images of implantation in each case. Range of motion for each segment (L2-3, L3-4, L4-5, and L5-S1) was measured independently for flexion, extension, right and left lateral bending, and for right and left rotation under 10 Nm pure moment. The mean and standard deviation of ROM for various cases tested were computed ($n = 6$). Statistical analysis using the paired T-test (Minitab) was performed on the kinematic data to determine the significance of multiple pair-wise comparisons. Testing hypotheses were considered statistically significant at P values below 0.05. Using statistical data, the following two hypotheses were investigated:

Hypothesis 1: The implanted cases have significantly decreased motion compared to intact cases.

Hypothesis 2: The bilateral approach using lag screws with or without cages provided less stability than did the traditional pedicle screw approach.

Results

Results of the biomechanical tests are summarized in Figures 6–8, and statistical analysis data are shown in Table 3. Figure 6 shows the range of motion (ROM) data in response to the applied 10 Nm moments. They represent the mean data of six specimens. We showed that the instrumented cases reduced the motion across the segment more than did the intact cases. The percentage of reduced motion was more for flex, ext and lateral bending cases but was less for left and right rotations.

Compared to the intact, the **PSS at L45 decreased** the motion of the segments in flex (68%), ext (58%), lb (53%), rb (62%), lr (22%) and rr (15%). Compared to the intact, the **IOTF at L45 decreased** the motion of the segments in flex (47%), ext (34%), lb (33%), rb (42%), lr (29%) and rr (25%). Compared to the intact, the **IOTF with TLIF cages at L45 decreased** the motion of the segments in flex (56%), ext (46%), lb (50%), rb (52%), lr (26%) and rr (25%).

Compared to the intact, the **PSS with TLIF cages at L45 decreased** the motion of the segments in flex (73%), ext (58%), lb (56%), rb (61%), lr (38%) and rr (36%).

The motion at L4-L5 was significantly reduced in all loading modes except right rotation (Table 3), when the segment was instrumented with the standard pedicle screw system (PSS). The motion at L4-L5 was significantly reduced in all loading modes except in left rotation, when the segment was instrumented with IOTF (Table 3). The motion at L4-L5 was significantly reduced in all loading modes except in rotations, when the segment was instrumented with IOTF + TLIF cages (Table 3). The motion at L4-L5 was significantly reduced in all loading modes when the segment was instrumented with PSS + TLIF cages (Table 3). There

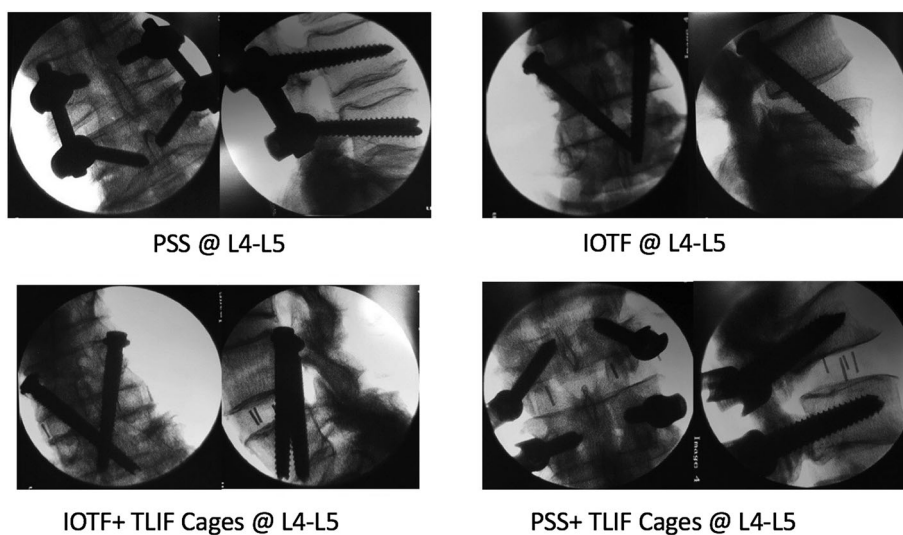
Table 2 Implants information showing the sizes of different implants used for each specimen (H: height, L: length, D: diameter).

ID	PSS		IOTF	IOTF + TLIF Cages		PSS + TLIF Cages		
	<i>Pedicle screws (4)</i>	<i>ROD (2)</i>		<i>Screws (2)</i>	<i>Screws (2)</i>	<i>Cages (2)</i>	<i>Pedicle Screws (4)</i>	<i>ROD (2)</i>
66814	D = 5.5 mm	D = 6 mm	D = 8-6.4 mm	D = 8-6.4 mm	9 × 22 (HxL) mm	D = 6.5 mm, L = 50 mm	D = 6 mm	9 × 22 (HxL) mm
	L = 50 mm	L = 50 mm	tapered, L = 70 mm	tapered, L = 70 mm		D = 6.5 mm, L = 50 mm	L = 50 mm	
66310	D = 5.5 mm	D = 6 mm	D = 8-6.4 mm	D = 8-6.4 mm	10 × 22 (HxL) mm	D = 6.5 mm, L = 50 mm	D = 6 mm	10 × 22 (HxL) mm
	L = 50 mm	L = 50 mm	tapered, L = 70 mm	tapered, L = 70 mm		D = 6.5 mm, L = 50 mm	L = 50 mm	
66568	D = 5.5 mm	D = 6 mm	D = 8-6.4 mm	D = 8-6.4 mm	8 × 22 (HxL) mm	D = 6.5 mm, L = 50 mm	D = 6 mm	8 × 22 (HxL) mm
	L = 50 mm	L = 50 mm	tapered, L = 70 mm	tapered, L = 70 mm		D = 6.5 mm, L = 50 mm	L = 50 mm	
68153	D = 5.5 mm	D = 6 mm	D = 8-6.4 mm	D = 8-6.4 mm	7 × 22 (HxL) mm	D = 6.5 mm, L = 50 mm	D = 6 mm	7 × 22 (HxL) mm
	L = 50 mm	L = 50 mm	tapered, L = 70 mm	tapered, L = 70 mm		D = 6.5 mm, L = 50 mm	L = 50 mm	
65177	D = 5.5 mm	D = 6 mm	D = 8-6.4 mm	D = 8-6.4 mm	8 × 22 (HxL) mm	D = 6.5 mm, L = 50 mm	D = 6 mm	8 × 22 (HxL) mm
	L = 50 mm	L = 50 mm	tapered, L = 70 mm	tapered, L = 70 mm		D = 6.5 mm, L = 50 mm	L = 50 mm	
66267	D = 5.5 mm	D = 6 mm	D = 8-6.4 mm	D = 8-6.4 mm	8 × 22 (HxL) mm on right side and 10 × 22 (HxL) mm on left side	D = 6.5 mm, L = 50 mm	D = 6 mm	8 × 22 (HxL) mm on right side and 10 × 22 (HxL) mm on left side
	L = 50 mm	L = 50 mm	tapered, L = 70 mm	tapered, L = 70 mm		D = 6.5 mm, L = 50 mm	L = 50 mm	

was no significant increase/decrease in ROM at the other levels due to implantation at L4-L5 (Figures 5 and 7).

On overall comparison, both systems yielded similar biomechanical results. However, when the outcomes

were analyzed separately, the new system (IOTF) without interbody fusion offered more rigidity in rotation than did the classical system. When both PSS and IOTF cases without cages were compared, the

**Figure 5** Fluoroscopic images showing implantation.

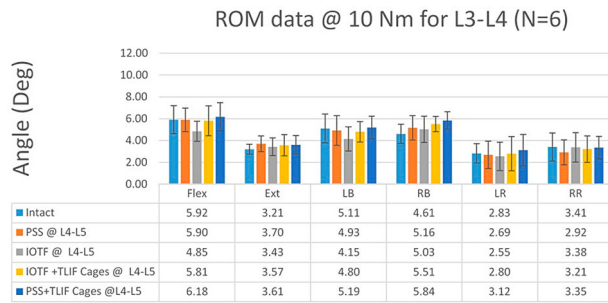


Figure 6 Mean range of motion of L3-L4 segment.

PSS performed better than did the IOTF in flexion and lateral bending (Table 3). When PSS and IOTF cases with cages were compared, there was no significant difference between the techniques (Table 3).

The results offered by our new system seem encouraging, and the biomechanical efficacy would be even higher in live human subjects since most of the cadaveric specimens were osteoporotic and pedicle-corpus junctions would have been weakened severely due to multiple trials in the course of the experiment.

Discussion

Spine surgeons have performed posterior lumbar segmental instrumentation using pedicle screwing techniques for posterior vertebral column fixation and fusion in degenerative spine diseases, traumatic and congenital/acquired spinal deformities. Adjacent segment disease is one of the most challenging conditions after fusion surgery. If revision surgery is needed; there are two surgical options: first, total exploration of the existing system, adding two screws with replacement of rods; and second, adding two screws and rods with a domino. However, there are some restrictions of these options, including extensive incision, more muscle dissection and longer operation time for the former option, and displacement of rods from a domino for the latter option.

Currently, spinal instrumentation is most commonly performed using the transpedicular screw and rod

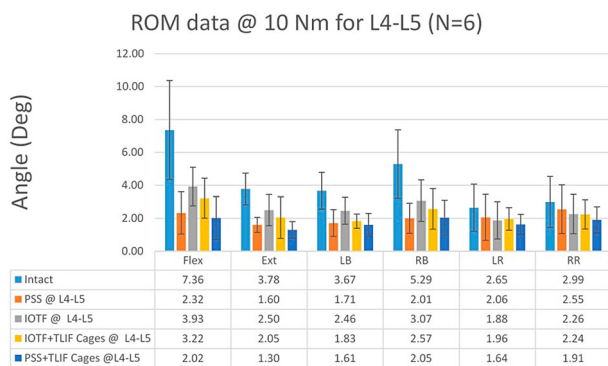


Figure 7 Mean range of motion of L4-L5 segment.

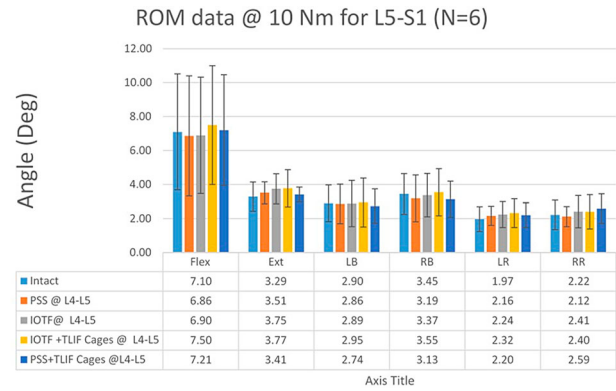


Figure 8 Mean range of motion of L5-S1 segment.

system that was popularized by Cotrel and Dubousse⁶. This same technique with some minor modifications has also widely been used for the correction of spinal deformities. Nevertheless, despite advanced surgical technique and neuromonitoring capabilities, malposition of screws and the risk of a resultant neurological deficit remains a major concern. In short, the classical transpedicular system is associated with the following drawbacks: screw loosening, particularly at the L5-S1 level; extensive paravertebral muscle dissection; malposition of screws and resulting dural sac and nerve root injuries and CSF fistulae; difficulty in revision surgeries; and potential need for domino placement in case of adjacent segment involvement.^{7,8} In this context, a safer technique with a reasonably long trajectory from dural sac and nerve roots is needed. Thus, we aimed to develop such a technique that may fulfill this crucial requirement. We named this new technique “inferior oblique transdiscal fixation”, as this approach enabled fixation of two adjacent vertebrae using a single screw on each side.

In this study, we compared the biomechanical efficacy of the classical posterior transpedicular technique with a

Table 3 P-values showing statistical significance ($P < 0.05$).

Compared to Intact	Flex	Ext	LB	RB	LR	RR
PSS @ L4-L5	0.01	0.01	0.00	0.00	0.00	0.06
IOTF @ L4-L5	0.02	0.03	0.01	0.01	0.59	0.04
IOTF + TLIF Cages @ L4-L5	0.01	0.01	0.02	0.01	0.10	0.10
PSS + TLIF Cages @ L4-L5	0.01	0.00	0.01	0.01	0.05	0.05
Compared to PSS @ L4-L5	Flex	Ext	LB	RB	LR	RR
IOTF @ L4-L5	0.04	0.12	0.01	0.02	0.38	0.20
Compared to IOTF + TLIF Cages @ L4-L5	Flex	Ext	LB	RB	LR	RR
PSS + TLIF Cages @ L4-L5	0.08	0.20	0.46	0.05	0.12	0.35

novel surgical technique (IOTF) with and without interbody fusion on fresh human lumbar cadaveric specimens. IOTF was equally effective to classical transpedicular fixation in terms of stabilization of instable spinal segment.

The new proposed surgical technique offered superiority in some aspects to the classical pedicle screw technique, including easy revision surgery, no need for domino placement, tri-cortical fixation and less risk of loosening of screws, safer trajectory with regard to the risks of dural sac and root injuries, shorter incisions, less paravertebral muscle and soft tissue dissection; possibility of interbody fusion and shorter duration of hospitalization. The other advantage of this new technique was the fact that it did not require a longer learning curve.

A disadvantage of this new technique would be the potential need for exiting nerve root retraction during screw placement. On the other hand, this technique would not be useful for deformity surgery because of the absence of correction maneuvers.

In our opinion, this new technique could be potentially used for the stabilization of painful black disc disease with intact corpus height, unstable recurrent disc herniation, low-grade degenerative spondylolisthesis, and decompressed lumbar spinal stenosis. A C-arm should be used in order to delineate the accurate trajectory of the screw during the procedure. In summary, we firmly believe that IOTF could be an effective alternative to classical transpedicular fixation in selected cases. In the future, we are planning to publish a clinical study demonstrating the preliminary outcomes of this new technique over two years.

Conclusions

The biomechanical results of the proposed new posterior fusion technique IOTF appeared to be encouraging and comparable to those of the classical pedicle screw technique. This preliminary study demonstrated the effect of the new posterior lumbar fixation technique that can be potentially useful and even superior in specific situations, including adjacent segment involvement and revision surgeries. The next step would be to test the efficacy of this technique in live human subjects.

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Contributors None

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Conflict of interest N/A

Ethics approval None

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